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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/736,047 | 12/15/2003 | Jacob A. Flagle | 8627/44 | 4057 |

7590 05/18/2006

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EXAMINER

FOREMAN, JONATHAN M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3736

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/736,047

Applicant(s)

FLAGLE ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In regards to claim 7, the specification fails to disclose the use of a curvilinear distal portion in conjunction with a coating that commences within the taper portion. Paragraphs [0044] and [0045] teach the use of a curvilinear distal portion with a coating that commences proximal to the tapered portion.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 26 - 28 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,040,543 to Badera et al.

In regards to claims 26 - 28, Badera et al. discloses a guidewire having an elongate member (4) including a proximal and distal end (8), the proximal end having a first outer diameter; and a coating (6) disposed on the distal end (8) of the elongate member (Figure 2), the coating comprising a flexible tip extending beyond the distal end (Col. 4, lines 41 – 44) and a solid member (12) spaced from the distal end, the coating having a second diameter that is approximately equal to or less than the first outer diameter (Col. 4, line 66 – Col. 5, line 8) wherein a portion of the coating is disposed between the distal end and the solid member (Figure 1). The solid member is made of a radiopaque material (Col. 3, lines 28 – 29).

5. Claims 26 – 28 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,095,915 to Engelson.

In regards to claims 26 - 28, Engelson discloses a guidewire having an elongate member (Figure 2) including a proximal (40) and distal end (42), the proximal end having a first outer diameter (Col. 3, lines 62 – 65); and a coating (44) disposed on the distal end (42) of the elongate member (Col. 4, lines 10 – 15), the coating comprising a flexible tip extending beyond the distal end (Figure 2) and a solid member (47) spaced from the distal end, the coating having a second diameter that is approximately equal to or less than the first outer diameter wherein a portion of the coating is disposed between the distal end and the solid member (Figure 2). The solid member is made of a radiopaque material (Col. 4, lines 62 - 66).

6. Claims 1 – 10, 21 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,340,441 to Meyer et al.

In regards to claims 1 – 10, 21 and 25, Meyer et al. discloses an elongate member (Figure 1) having a proximal end (12), a main body having a first diameter (Col. 3, lines 20 – 22), a distal end (14) having a second diameter, and a taper portion (20) disposed directly between the main body and

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a distal end and defining a taper between the first and second diameters (Col. 3, lines 43 – 47); and a coating (32, 34) disposed on the distal end and comprising a flexible tip having a length axially extending beyond the distal end, the ratio of the length to the first diameter being greater than 3:1 (Col. 4, lines 5 – 8), the coating having a proximal portion and a distal portion, the proximal portion commencing within the taper portion of the elongate member (Col. 3, lines 48 – 51). Meyer et al. discloses the length of the flexible tip being greater than 3mm (Col. 4, lines 5 – 8). The coating comprises an outer diameter approximately equal to or less than the first diameter (Col. 4, lines 9 – 14). The elongate member is either stainless steel or nitinol (Col. 3, lines 30 – 33). A lubricious coating is disposed on a portion of the main body (Col. 4, lines 33 – 35). The flexible tip comprises radiopaque material (Col. 3, lines 56 – 61). A solid marker is disposed in the flexible tip and a portion of the coating is disposed between the distal end of the elongate member and the marker in that the flexible tip is impregnated with radiopaque materials (Col. 3, lines 56 – 61). The flexible tip comprises a curvilinear distal portion (Col. 3, lines 35 – 36).

7. Claims 1 - 28 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application No. 2004/0087876 to Eskuri.

In regards to claims 1 – 28, Eskuri discloses an elongate member (Figure 1) having a proximal end (20), a main body having a first diameter, a distal end (22) having a second diameter, and a taper portion disposed directly between the main body and a distal end and defining a taper between the first and second diameters [0017] [0018]; and a coating [0022] – [0024] disposed on the distal end and comprising a flexible tip having a length axially extending beyond the distal end, the ratio of the length to the first diameter being greater than 3:1 and between 12:1 and 250:1 [0018][0028][0029], the coating having a proximal portion and a distal portion, the proximal portion commencing within the taper portion of the elongate member (Figure 1). Eskuri discloses the

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length of the flexible tip being greater than 3mm [0028][0029]. The length of the flexible tip extending beyond the distal tip is greater than the length of the distal tip [0020][0028][0029]. The elongate member is either stainless steel or nitinol [0016]. A lubricious coating is disposed on a portion of the main body [0030]. The flexible tip comprises radiopaque material [0026]. A solid marker is disposed in the flexible tip and a portion of the coating is disposed between the distal end of the elongate member [0026]. The flexible tip comprises a curvilinear distal portion [0023].

Response to Arguments

8. Applicant's arguments filed 2/15/06 have been fully considered but they are not persuasive. Applicant asserts that Badera et al. (US Patent No. 5,040,543) fails to disclose "the coating comprising a flexible tip extending beyond the distal end and encompassing a solid member, the solid member being spaced from the distal end". However, claim 26 does not require the coating to encompass the solid member.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JMLF



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